NAPROXEN SODIUM- naproxen sodium tablet, coated
Dr.Reddy's Laboratories Limited

NAPROXEN SODIUM
TABLETS USP, 220 mg

PAIN RELIEVER / FEVER REDUCER (NSAID)

Drug Facts

Active ingredient (in each tablet/caplet)

Naproxen sodium USP, 220 mg
(naproxen USP, 200 mg) (NSAID)[1]

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1 nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscular aches
  - backache
  - menstrual cramps
  - headache
  - toothache
  - the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks everyday while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- If you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor’s care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest paint
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- drink a full glass of water with each dose

Adults and children 12 years and older	▪ take 1 tablet/caplet every 8 to 12 hours while symptoms last ▪ for the first dose you may take 2 tablets/caplets within the first hour ▪ do not exceed 2 tablets/caplets in any 8 to 12 hour period ▪ do not exceed 3 tablets/caplets in a 24-hour period
Children under 12 years	▪ ask a doctor

Other information

- **each tablet/caplet contains:** sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients

FD &C Blue # 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, talc, titanium dioxide

Questions or comments?

call toll-free weekdays 9 AM to 8 PM EST at **1-888-375-3784**

Distributed by:

Dr. Reddy’s Laboratories, Inc.

Princeton, NJ 08540

Made in India

Rev: 03/2022

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL SECTION

Caplets

Container

Top
(PNL 1)

Dr.Reddy's NDC 55111-273-24

Naproxen Sodium
Tablets USP, 220 mg (NSAID)

Pain reliever / fever reducer

STRENGTH TO LAST 12 HOURS

24 Caplets
(CAPSULE-SHAPED TABLETS)

TAMPER EVIDENT: Do not use if foil seal under cap printed with "sealed for your protection" is broken or missing.
IMPORTANT: Read the directions and warnings before use.
See carton for Full Information

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, or blisters. If an allergic reaction occurs, stop use and seek medical help right away. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you:
■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed. ▲

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Princeton, NJ 08540
Made in India

Rev: 03/2022

LOT
EXP 15OOXXXXX

Peel Here

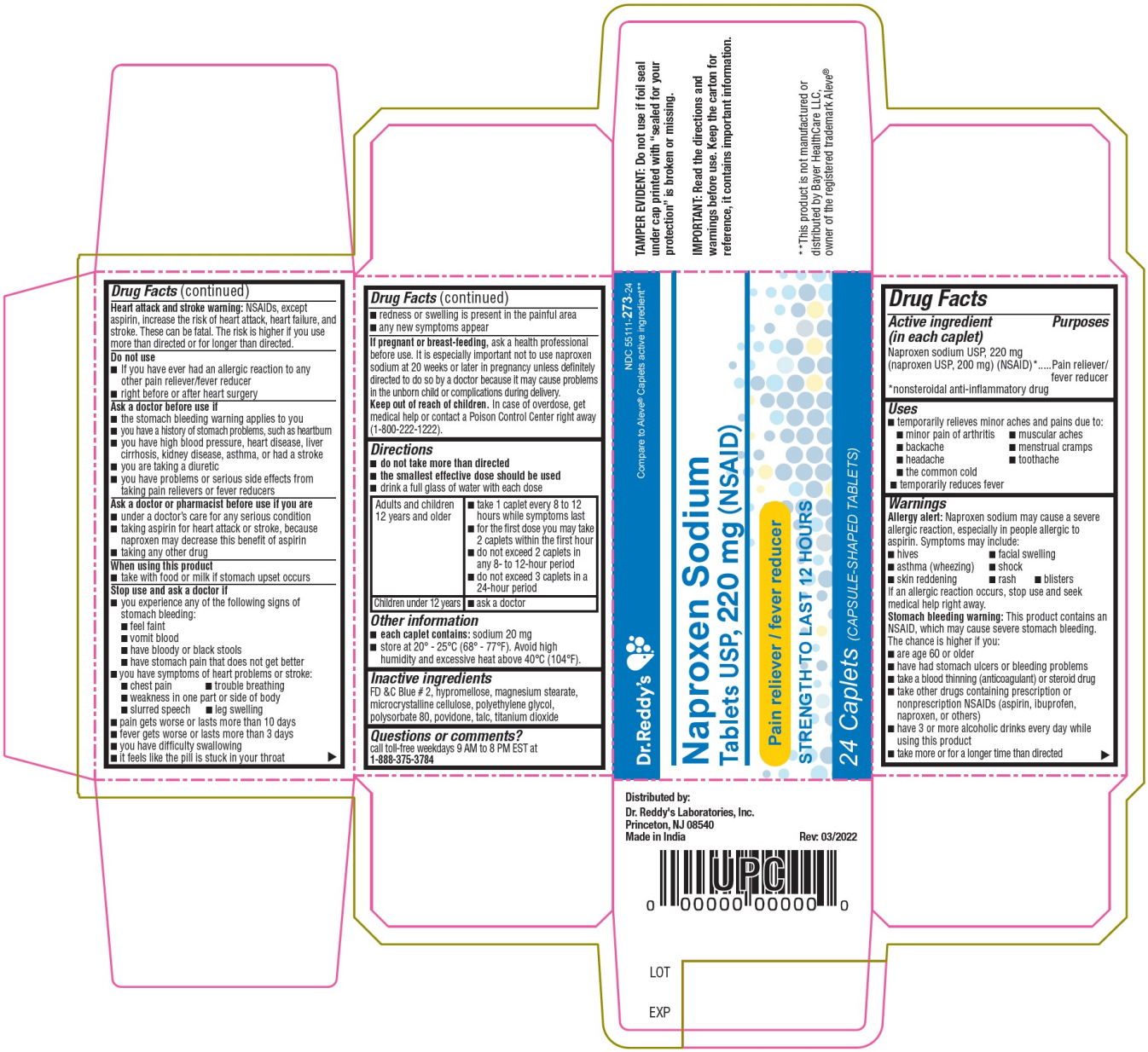
Top Inside
(PNL 2)

Heart attack and stroke warning: NSAIDs except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer or right before or after heart surgery. **Ask a doctor before use** if the stomach bleeding warning applies to you, you have a history of stomach problems (such as heartburn), you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke, you are taking a diuretic, you have problems or serious side effects from taking pain relievers or fever reducers. **Ask a doctor or pharmacist before use if you are** under a doctor's care for any serious condition, or taking any other drug. **When using this product** take with food or milk if stomach upset occurs. **Stop use and ask a doctor if** you experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better), you have symptoms of heart problems or stroke (chest pain, ▲

Bottom
(PNL 3)

trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, you have difficulty swallowing, it feels like the pill is stuck in your throat, redness or swelling is present in the painful area, or any new symptoms appear.
If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).
Directions **Do not take more than directed. The smallest effective dose should be used.** Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 caplet every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 2 caplets in any 8- to 12-hour period. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor.
Other Information Each caplet contains: sodium 20 mg. Store at 20°-25°C (68°-77°F). Avoid high humidity and excessive heat above 40°C (104°F).
Questions or comments? call toll-free weekdays 9 AM to 8 PM EST at 1-888-375-3784

Container Carton



Tablets

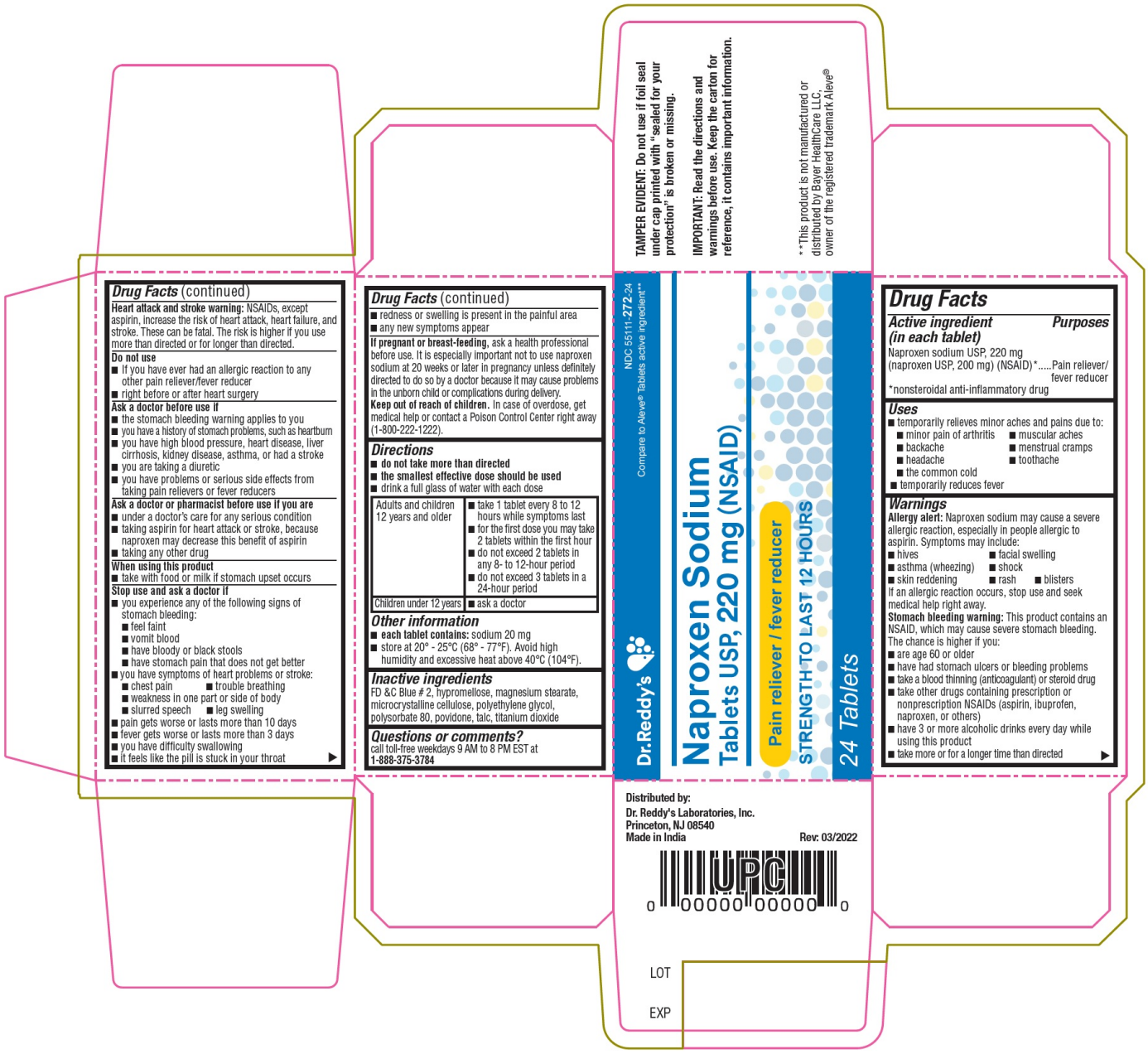
Container

Top (PNL 1)

Top Inside (PNL 2)

Bottom (PNL 3)

Container Carton



NAPROXEN SODIUM

naproxen sodium tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55111-272
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Naproxen Sodium (UNII: 9TN87S3A3C) (Naproxen - UNII:57Y76R9ATQ)	Naproxen Sodium	220 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
hypromelloses (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
cellulose, microcrystalline (UNII: OP1R32D61U)	
Polyethylene Glycol, Unspecified (UNII: 3WQ0SDW1A)	
povidone (UNII: FZ989GH94E)	
talc (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	R;272
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-272-24	1 in 1 CARTON	07/29/1998	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55111-272-50	1 in 1 CARTON	07/29/1998	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55111-272-01	1 in 1 CARTON	07/29/1998	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:55111-272-02	1 in 1 CARTON	07/29/1998	
4		200 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:55111-272-05	1 in 1 CARTON	07/29/1998	
5		500 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075168	07/29/1998	

NAPROXEN SODIUM

naproxen sodium tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55111-273
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Naproxen Sodium (UNII: 9TN87S3A3C) (Naproxen - UNII:57Y76R9ATQ)	Naproxen Sodium	220 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
hypromelloses (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
cellulose, microcrystalline (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
povidone (UNII: FZ989GH94E)	
talc (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	CAPSULE	**Size**	12mm
Flavor		**Imprint Code**	R;273
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-273-24	1 in 1 CARTON	07/29/1998	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55111-273-50	1 in 1 CARTON	07/29/1998	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55111-273-01	1 in 1 CARTON	07/29/1998	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:55111-273-02	1 in 1 CARTON	07/29/1998	
4		200 in 1 BOTTLE; Type 0: Not a Combination		

4		Product		
5	NDC:55111-273-40	1 in 1 CARTON	07/29/1998	
5		400 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:55111-273-05	1 in 1 CARTON	07/29/1998	
6		500 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075168	07/29/1998	

Labeler - Dr.Reddy's Laboratories Limited (650562841)

Revised: 12/2022 Dr.Reddy's Laboratories Limited